

Data Sheet

CellGenix® GMP Recombinant Human Tumor Necrosis Factor-alpha (rh TNF-α)

Order No.: 1006-050 (50 µg)

Product Characteristics

Source	<i>E. coli</i>
Description	Human TNF-alpha, accession # P01375, Val77-Leu233 N-terminal Met Molecular mass 17.5 kDa
Formulation	Lyophilized from a 0.2 µm-filtered solution containing 1.5 mM potassium phosphate, 8.1 mM sodium phosphate, 2.7 mM potassium chloride and 137 mM sodium chloride, pH 7.5.
Intended use	For further manufacturing use.

Quality Parameters

Identity	Confirmed by DNA-sequencing of the expression plasmid in end-of-production cells and N-terminal sequencing of the final product
Activity	20 - 80 x 10 ⁶ IU/mg calibrated against current NIBSC reference standard Measured in a cell cytotoxicity assay using a TNF-α-sensitive cell line, L929
Purity	≥ 97 %, as determined by SDS-PAGE (under reducing and non-reducing conditions, visualized by Coomassie staining)
Product-related proteins	≤ 10 % oligomers as determined by SDS-PAGE (under non-reducing conditions, visualized by Coomassie staining)
Host-cell DNA	≤ 200 ng/mg, as determined with a fluorimetric assay
Host-cell protein	≤ 1.0 µg/mg, as determined by ELISA
Endotoxin	≤ 50 EU/mg, as determined by LAL gel clot test according to Ph. Eur. and USP
Sterility	Sterility test according to Ph. Eur. and USP of the vial product
Mass per vial	43 - 57 µg, as determined by spectrophotometrical measurement
Animal-derived component-free	ADCF Level 2: The final product contains neither animal- nor human-derived materials. ADCF Level 2 cytokines are produced in our dedicated animal-free facility. No animal-derived components are used throughout the complete production process. All ADCF Level 2 cytokines are produced in <i>E. coli</i> .

Shipment & Storage

Transport	Ambient temperature. Please refer to Technote (www.cellgenix.com)
Shelf life	Minimum 6 months from date of shipping
Storage & Stability	<p>Store lyophilized cytokine at -20 °C to -80 °C.</p> <ul style="list-style-type: none">• Store a 250 µg/ml reconstituted cytokine solution for 4 weeks at 2 °C to 8 °C under sterile conditions after reconstitution. Store in the original container.• Store a 100 µg/ml reconstituted cytokine solution for 4 months at -20 °C to -80 °C under sterile conditions after reconstitution. Store in aliquots in polypropylene cryogenic vials. <p>Avoid repeated freeze/thaw cycles.</p>

Handling Instructions

Reconstitution	Recommended in sterile water to a final concentration of 250 µg/ml.
Dilution	Recommended in CellGenix® serum-free media. For dilution with protein free medium, a carrier protein (0.1-1 % albumin or 1-10 % appropriate serum) has to be included. Failure to dilute product according to these instructions may result in loss of activity.

Quality Statement

This product is manufactured, tested and released in compliance with the relevant GMP-guidelines. No animal- or human-derived components are present in the final product and no animal- or human-derived materials were used in production (ADCF Level 2). USP chapter <1043> has been considered in the design of this product. This product is compliant with Ph. Eur. general chapter 5.2.12 and ISO 20399:2022.